

## **II. Rationale and support for the amendment**

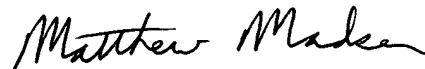
Claims 23-27 are cancelled as being drawn to a non-elected invention. The remaining amendments are made to focus and simplify examination of the claims in order to expedite allowance thereof. Accordingly, Applicant explicitly reserves the right to pursue the cancelled material in one or more continuation or divisional applications. Support for the amendment of claim 3 is found in the specification at page 10, lines 26-29.

## **III. Response to the Restriction Requirement**

In response to the restriction requirement which the Examiner imposed, Applicant elects, without traverse, to prosecute claims 1-22, *i.e.*, the Group I claims.

The Examiner is invited to contact the undersigned patent agent at (713) 787-1589 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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## CLAIMS:

1. **(Amended)** A composition of matter, comprising:
  - c) somatotropin;
  - d) a first bioavailability enhancing constituent (BEC); and,
  - c) optionally, a second BEC;wherein the first BEC is ~~{selected from}~~ a non-ionic surfactant; ~~{or a cyclodextrin, and}~~  
wherein the second BEC is selected from one or a mixture of two or more of the following: ~~{a} one or more non-reducing carbohydrate(s) {carbohydrate, an amino acid, an amino acid derivative, an amino acid polymer, an hydroxamate or hydroxamate derivative, or an}~~ and one or more oxo-acid {salt} salt(s); and,  
wherein the somatotropin and BEC are suspended in a substantially non-aqueous hydrophobic carrier.
2. A composition of matter, of claim 1, wherein the first BEC surfactant is selected from one or a mixture of two or more of the following: polyoxyethylene fatty acids esters, poloxamers, polyoxyethylene sorbitan fatty acid esters, tocopherol polyethylene glycol succinates, sugar fatty acid esters, polyoxyethylene glycerides, and polyoxyethylene vegetable oils.
3. **(Amended)** The composition of either claim 1 or 2, wherein the ~~{somatotropin and bioavailability enhancing constituent(s) are suspended in a substantially non-aqueous hydrophobic carrier}~~ composition is fluidly injectable at 37°C to 39°C.
4. **(Amended)** The composition of matter of either claim 1 or 2 ~~{3}~~, wherein the somatotropin is present as a zinc salt or complex.
5. **(Amended)** The composition of matter of either claim 1 or 2 ~~{3}~~, wherein the somatotropin is human, equine, bovine, or porcine somatotropin.

6. **(Amended)** The composition of matter of either claim 1 or 2 {3}, wherein the second bioavailability enhancing constituent is a non-reducing carbohydrate selected from one or a mixture of two or more of the following: at least one polyol ~~for~~ and at least one carbohydrate ester.
7. **(Amended)** The composition of matter of ~~either~~ claim 6, wherein the second bioavailability enhancing constituent is selected from one or a mixture of two or more of the following: trehalose, sucrose, mannitol, sorbitol, trehalose octaacetate, trehalose dihydrate, sucrose octaacetate, and cellobiose octaacetate.
8. The composition of matter of claim 7, wherein the first BEC is present at from about 0.1% to about 10%, by weight, of the composition and the second BEC is present at from about 1% to about 20%, by weight, of the composition.
9. The composition of matter of claim 8, wherein the somatotropin is bovine somatotropin present at about 10-50%, by weight, of the composition, and wherein the substantially non-aqueous hydrophobic carrier is comprised of about 95% sesame oil and about 5%, by weight, aluminum monostearate.
10. **(Amended)** The composition of matter of either claim 1 or 2 {3}, wherein the second bioavailability enhancing constituent (BEC) is selected from one or a mixture of two or more ~~{of the following: an amino acid, an amino acid derivative, an amino acid polymer, a hydroxamate derivative, or an}~~ oxo-acid salt(s) {salt}.
11. **(Amended)** The composition of matter of either claim 10, wherein the second BEC is selected from one or a mixture of two or more of the following: ~~{histidine, histidine HCl, a histidine derivative, polyhistidine, arginine, lysine, tryptophan, glycine, histidine hydroxamate, suberohydroxamic acid, salicyl hydroxamic acid, bufexamac acid, eaprylohydroxamic acid,}~~ monobasic potassium phosphate, dibasic potassium phosphate, monobasic calcium phosphate, dibasic calcium phosphate, sodium nitrate, and dibasic sodium sulfate~~[-phosphate salts, nitrate salts, and sulfate salts]~~.

12. The composition of matter of claim 11, wherein the first BEC is present at from about 0.1% to about 10%, by weight, of the composition and the second BEC is present at from about 1% to about 15%, by weight, of the composition.
13. The composition of matter of claim 12, wherein the somatotropin is bovine somatotropin present at about 10-50% and wherein the substantially non-aqueous hydrophobic carrier is comprised of about 95% sesame oil and about 5%, by weight, aluminum monostearate.
14. **(Amended)** A composition of matter, comprising:
  - c) somatotropin,
  - d) a first bioavailability enhancing constituent (BEC), and,
  - c) optionally, a second BEC;
 wherein the first BEC comprises one or a mixture of two or more of the following: polyoxyethylene 4 stearate, polyoxyethylene 8 stearate, polyoxyethylene(20) sorbitan monooleate (Tween® 80), ~~hydroxypropyl beta cyclodextrin, and~~;
 wherein the second BEC is selected from one or a mixture of two or more of the following: one or more non-reducing carbohydrate(s) [carbohydrate, amino acid, amino acid derivative, amino acid polymer, hydroxamate or hydroxamate derivative, or an] and one or more oxo-acid [salt] salt(s); and,
wherein the somatotropin and BEC are suspended in a substantially non-aqueous hydrophobic carrier.
15. The composition of claim 14, wherein the first BEC comprises polyethyleneoxide 8 stearate (POE8S).
16. The composition of claim 15, wherein the POE8S is present at a concentration of from about 0.1 to about 10%, by weight, of the composition.
17. **(Amended)** The composition of claim 15, further comprising a second BEC, wherein the second BEC ~~[is comprised of]~~ selected from one or a mixture of two or more of the following: trehalose, ~~[histidine-HCl,]~~ monobasic sodium phosphate, and a mixture of monobasic- and dibasic-sodium phosphate in about a 6:4 molar ratio.

18. **(Amended)** A method for eliciting a desired physiological response in a susceptible animal comprising:  
parenterally administering to the animal a biocompatible composition of matter comprising:  
a) a somatotropin, active in the animal;  
b) a first bioavailability enhancing constituent (BEC); and,  
c) optionally, a second BEC;  
wherein the first BEC is selected from a non-ionic surfactant ~~{or a cyclodextrin, and}~~;  
wherein the second BEC is selected from one or a mixture of two or more of the following: ~~{a} one or more non-reducing carbohydrate(s) {carbohydrate, an amino acid, an amino acid derivative, an amino acid polymer, an hydroxamate or hydroxamate derivative, or an} and one or more oxo-acid salt(s) {salt}; and,~~  
wherein the somatotropin and BEC are suspended in a substantially non-aqueous hydrophobic carrier.
19. **(Amended)** The method of 18, wherein the first BEC ~~{comprises}~~ is selected from one or a mixture of two or more of the following: polyoxyethylene 4 stearate, polyoxyethylene 8 stearate, and polyoxyethylene(20) sorbitan monooleate (Tween® 80)~~{, hydroxypropyl beta-cyclodextrin}~~.
20. The method of claim 19, wherein the first BEC comprises polyethyleneoxide 8 stearate (POE8S).
21. The composition of claim 20, wherein the POE8S is present at a concentration of from about 0.1 to about 10%, by weight, of the composition.
22. **(Amended)** The composition of claim 20, further comprising a second BEC, wherein the second BEC is ~~{comprised of}~~ selected from one or a mixture of two or more of the following: trehalose, ~~{histidine-HCl,}~~ monobasic sodium phosphate, and mixture of monobasic- and dibasic-sodium phosphate in about a 6:4 molar ratio.